

Appl. No. : 09/435,562
Filed : November 8, 1999

REMARKS

Claims 38-45, 51-98, 101, 106-109, and 129-134 were pending. With the present amendment Claims 101 and 131 are amended; therefore, Claims 38-45, 51-98, 101, 106-109, and 129-134 remain pending for consideration.

Allowable Subject Matter

Applicants would like to thank the Examiner for his thorough review of the present application and for the allowance of Claims 38-45, 51-98, 129 and 130. Applicants would also like to thank the Examiner for the indication of allowable subject matter in Claim 106.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 101 and 107-109

Claims 101 and 107-109 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,928,260 to Chin, et al. in view of U.S. Patent No. 6,258,115 to Dubrul. Applicants respectfully traverse the rejection.

Claim 101 describes, *inter alia*, a device for implantation within a left atrial appendage of a patient, the device comprising an expandable frame and an endothelialization membrane, wherein the device is adapted to be separated from a delivery device to be implanted within the left atrial appendage.

Section 2143 of the M.P.E.P. states that to establish *prima facie* obviousness three requirements must be met:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the Applicant's disclosure.

Because the references cited by the Examiner do not disclose, teach or suggest, *inter alia*, a device adapted to be separated from a delivery device to be implanted within the left atrial appendage, Claim 101 is not obvious in view of Chin and Dubrul. Furthermore, there is no suggestion or motivation, either in the references themselves or in the knowledge generally

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available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. In addition, there is no indicated reasonable expectation of success.

Therefore, Claim 101 is allowable over the cited art. Claims 107-109 depend from Claim 101 and are therefore allowable for at least these reasons as well. In addition, Claims 107-109 are allowable for the unique features described therein. Applicants respectfully request allowance of these claims.

Claims 131-134

Claims 131-134 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,374,512 to Cottenceau, et al. in view of U.S. Patent No. 6,110,243 to Wnenchak, et al. Claims 131-134 are also rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,853,422 to Huebsch in view of U.S. Patent No. 5,961,545 to Lentz, et al.

Claim 131 describes, *inter alia*, a device for implantation within a left atrial appendage of a patient, the device comprising: an expandable frame having a generally cylindrical configuration when fully expanded having a proximal end and a distal end, the frame sized and configured to be positioned at the left atrial appendage; and a membrane provided over and closing off the proximal end of the frame to prevent the passage of embolic material through the frame, wherein the membrane is made of ePTFE, and wherein the ePTFE membrane endothelializes after implantation.

There is no motivation to combine Cottenceau with Wnenchak and certainly no teaching or suggestion within the references themselves to make the proposed combination or that there would be a reasonable expectation of success in doing so. Rather, it appears that the Examiner has impermissibly used hindsight derived from the teachings in the present application, and not the teachings of the prior art, to reject Claim 131. In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999) (holding the Board impermissibly used hindsight in determining obviousness); see also, M.P.E.P. § 2145, part X.A. In Dembiczak the Federal Circuit reiterated that a determination of obviousness cannot simply rely on the inventor's disclosure as a "blueprint" without evidence of a suggestion, teaching or motivation in the prior art. Dembiczak, 175 F.3d 994, 999. Also, according to M.P.E.P. § 706.02(j), "[t]he teaching and suggestion to make the claimed

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combination and the reasonable expectation for success must both be found in the prior art and not based on the Applicant's disclosure." (emphasis added).

Cottenceau teaches an implantable blood filter intended to be placed or implanted in a vessel of the circulatory system, in order to retain therein possible blood clots. Cottenceau, col. 1, lines 5-8. Wnenchak teaches a cleanable filter bag assembly for applications such as dust collecting. Wnenchak, col. 6, lines 18-25. Wnenchak's bag is described as useful for various cleaning methods, including vibration, back pulsing, reverse air cleaning, sonic cleaning and shaking; however, nowhere does Wnenchak teach or suggest a motivation to use his bag in a medical application or as a blood filtering material. There would be no motivation to combine Cottenceau's blood filter with Wnenchak's filter bag and there is no indication that such combination could be successfully accomplished.

Furthermore, the ePTFE membrane of Claim 131 "endothelializes after implantation," which contradicts Cottenceau and Wnenchak's teachings. There would be no motivation to combine filtering references such as Cottonceau and Wnenchak when considering a device for implantation within the left atrial appendage comprising, inter alia, an ePTFE membrane that endothelializes after implantation.

There is simply no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. In addition, there is no indicated reasonable expectation of success in doing so.

The combination of Huebsch and Lentz fails to teach all of the claimed elements, including an expandable frame having a generally cylindrical configuration when fully expanded. Huebsch's frame, when fully expanded does not have a generally cylindrical configuration. See Huebsch, Figures 3, 4, 23, and 24. Not only does the combination of Huebsch and Lentz fail to teach all the claim limitation, but there is no suggestion or motivation to combine the references and no indicated reasonable expectation of success in doing so. In addition, there is no teaching or suggestion to combine and reasonable expectation of success provided by the cited references themselves.

Therefore, Claim 131 is patentable over the cited art, and Applicants respectfully request allowance of this claim. In addition, Claims 132-134 depend from Claim 131 and are therefore

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allowable for at least these reasons. In addition, Claims 132-134 are patentable for the unique features described therein.

CONCLUSION

Applicants submit that the present application is in condition for allowance, and such action is respectfully requested. The Examiner is invited to contact the undersigned Attorney of Record at the number provided below should any issues require further clarification, or if allowance of this case may be expedited by Examiner's Amendment.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: _____


Sabing H. Lee
Registration No. 43,745
Attorney of Record
Customer No. 20,995
(949) 760-0404

1935285
091505